IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NORTH CAROLINA

Civil Action No.: 5:13-cv-102

DISABILITY RIGHTS NORTH	
CAROLINA,)
Plaintiff,) FRYE REGIONAL MEDICAL CENTER,) INC.'S BRIEF IN SUPPORT OF MOTION
v.	TO DISMISS
FRYE REGIONAL MEDICAL CENTER,)
INC.)
)
Defendant	

Pursuant to Local Rule 7.1(C) and Rule 12(b)(6) of the Federal Rules of Civil Procedure, Frye Regional Medical Center, Inc. ("Frye Regional") respectfully submits this Brief in Support of its Motion to Dismiss. For the reasons set forth below, the motion should be granted and Plaintiff's Complaint should be dismissed.

NATURE OF THE MATTER BEFORE THE COURT

Frye Regional is an acute care hospital in Hickory, North Carolina. Disability Rights North Carolina ("Plaintiff") serves as the Protection and Advocacy ("P&A") agency for North Carolina pursuant to the Protection and Advocacy for Individuals with Mental Illness Act ("PAIMI Act" or "Act"), 42 U.S.C. §§ 10801-1085. The PAIMI Act provides federal funds for states, such as North Carolina, that have qualifying P&A systems that monitor the care of individuals with disabilities and mental illness in facilities providing care and treatment. *See* 42 U.S.C. § 10801. Plaintiff is conducting an investigation regarding a patient, C.L.H., with a diagnosis of mental disorder who passed away while receiving medical treatment.

Both North Carolina law and the PAIMI Act protect peer review materials from disclosure, with the PAIMI Act specifically providing that the Act is not "intended to preempt

State law protecting records produced by medical care evaluation or peer review committees." 42 C.F.R. § 51.41(c)(4). Nevertheless, Plaintiff seeks to compel disclosure of Frye Regional's peer-review privileged internal investigation reports, claiming that Frye Regional's refusal to waive its peer review privilege constitutes a violation of the PAIMI Act and of Plaintiff's "statutory rights" under the Act.

STATEMENT OF PERTINENT FACTS¹

According to the Complaint, C.L.H. was an individual with a diagnosis of psychosis who was a patient at Frye Regional. (Compl. ¶ 11.) Plaintiff alleges that on or about February 18, 2013, C.L.H. was involved in an altercation with Frye Regional staff. (*Id.* at ¶ 12.) According to Plaintiff's allegations, Frye Regional staff put C.L.H. into a restraint, resulting in C.L.H.'s sustaining a fractured leg. (*Id.*) Plaintiff alleges that on or about March 10, 2013, C.L.H. was evaluated for shortness of breath and chest pain. (*Id.*) According to the Complaint, tests revealed a large pulmonary embolus in C.L.H.'s right lung for which he was treated in the Intensive Care Unit. (*Id.*) Plaintiff alleges that on or about March 14, 2013, C.L.H. died at Frye Regional. (*Id.*)

According to Plaintiff's allegations, it received a report of C.L.H.'s death and initiated an investigation into the matter. (*Id.* at ¶¶ 12, 13.) Plaintiff alleges that as part of its investigation, it requested that Frye Regional disclose a variety of documents, including C.L.H.'s individual treatment records and Frye Regional's investigation records, including root-cause analyses and other peer review materials. (*Id.* at ¶ 14.) Plaintiff alleges that Frye Regional complied with the request and provided the materials except for documents protected by the peer review privilege.

2

¹ For purposes of a Rule 12(b)(6) motion, as is required, the factual allegations of the Complaint are taken as true. Frye Regional fully reserves the right to otherwise contest Plaintiff's factual allegations.

(Id. at ¶ 16.) Frye Regional declined to waive the peer review privilege. (Id.) This action then ensued, the sole purpose of which is to obtain peer review materials from Frye Regional.

QUESTIONS PRESENTED

I. SHOULD PLAINTIFF'S COMPLAINT BE DISMISSED WHEN IT FAILS TO ALLEGE FACTS THAT COULD ENTITLE PLAINTIFF TO RELIEF FROM FRYE REGIONAL?

ARGUMENT

I. PLAINTIFF'S COMPLAINT SHOULD BE DISMISSED FOR FAILING TO ALLEGE FACTS ENTITLING IT TO RELIEF FROM FRYE REGIONAL.

In its Complaint, Plaintiff alleges that Frye Regional's refusal to disclose peer review protected materials "violate[s] DRNC's statutory rights under the PAIMI Act," "irreparably harms DRNC by preventing it from carrying out its responsibilities under the Act," and renders DRNC "unable to protect and advocate for persons with disabilities." (*Id.* at ¶ 26, 27.) Plaintiff fails to articulate the "statutory rights" that are allegedly violated by Frye Regional's refusal to produce peer review protected materials. Plaintiff also fails to allege a single fact to support its allegations that, by declining to waive its statutory peer review privilege and provide materials to which the PAIMI Act expressly states Plaintiff is not entitled, Frye Regional has somehow stripped Plaintiff of its robust investigatory powers or prevented Plaintiff from exercising those powers.

A. Standard for Motion to Dismiss Pursuant to Rule 12(b)(6).

A motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure should be granted if, assuming the facts in the complaint are true, a plaintiff has not alleged facts that would entitle him to relief. *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th. Cir. 1999). Although "a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to

relief requires more than labels and conclusions[.]" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations and quotations omitted). When "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not shown—that the pleader is entitled to relief." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009) (internal quotations omitted). Furthermore, "[t]he court need not accept the legal conclusions drawn from the facts, and need not accept as true unwarranted inferences, unreasonable conclusions, or arguments." *Simmons v. United Mortg. & Loan Inv., LLC*, 634 F.3d 754, 768 (4th Cir. 2011) (quotation omitted).

B. The Records Sought by Plaintiff Are Privileged Peer Review Materials Under North Carolina State Law.

Under PAIMI, protection and advocacy groups have broad access to the records of mentally ill individuals. *See* 42 U.S.C. § 10805(a)(4). However, the United States Department of Health and Human Services ("HHS") promulgated regulations for the implementation of the PAIMI Act (the "HHS Rule") that specifically carve out an exception for peer review records that are protected by State law. The HHS Rule provides that a P&A system has broad rights of access to a range of materials in conducting an investigation, "except that nothing in this section is intended to preempt State law protecting records produced by medical care evaluation or peer review committees." 42 C.F.R. § 51.41(c)(4). North Carolina statutorily protects peer review records. *See* N.C. Gen. Stat. § 131E-95(b).

The records Plaintiff seeks to compel Frye Regional to disclose are records created by Frye Regional pursuant to the statutory peer review protection and are therefore privileged documents and not subject to Plaintiff's review. North Carolina law provides the following regarding records of peer review committees:

(b) The proceedings of a medical review committee, the records and materials it produces and the materials it considers

shall be confidential and not considered public records within the meaning of G.S. 132-1, "Public records' defined", and shall not be subject to discovery or introduction into evidence in any civil action against a hospital, an ambulatory surgical facility licensed under Chapter 131E of the General Statutes, or a provider of professional health services which results from matters which are the subject of evaluation and review by the committee.

N.C. Gen. Stat. § 131E-95(b). Identical language is found in the statutes governing the peer review functions of facilities, like Frye Regional, licensed under the North Carolina statutes to provide services to individuals who are mentally ill. *See*, *e.g.*, N.C. Gen. Stat. § 122C-30(2).

North Carolina courts have long recognized the important public policy considerations underpinning the peer review privilege. In *Cameron v. New Hanover Memorial Hospital*, 58 N.C. App. 414, 293 S.E.2d 291 (1982), the North Carolina Court of Appeals articulated those considerations, noting that the statutory peer review privilege:

was enacted upon the theory that external access to peer investigations conducted by staff committees stifles candor and inhibits objectivity . . . [medical peer review protection] represents a legislative choice between competing public concerns. It embraces the goal of medical staff candor at the cost of impairing plaintiffs' access to evidence. Our Supreme Court has long embraced this philosophy as the basis for the doctrine of privileged communications.

Cameron, 58 N.C. App. at 436, 293 S.E.2d at 914 (internal citation omitted). By promoting "candor and frank exchange," *Sheldon v. Morehead Memorial Hospital*, 318 N.C. 76, 82, 347 S.E.2d 824, 828 (1986), the statutory peer review protection encourages health care providers to fully and honestly evaluate situations that arise during patient care, identify areas for improvement, and implement action plans to ensure patient safety without fear that such honest self-evaluation will be used against them in a lawsuit or investigation.

Plaintiff argues that the peer review protection afforded under North Carolina law is only valid in the context of civil litigation. On its face, however, the PAIMI Act, in expressly

excluding peer review protected materials from the documents available to Plaintiff during the course of a P&A investigation, contradicts Plaintiff's position. Under the plain language of the PAIMI regulations, it is sufficient that the materials in question are recognized under State law as peer-review protected materials. Other federal agencies have adopted this position, as well. For example, the Centers for Medicare and Medicaid Services ("CMS"), in its "Guidance to Surveyors for Long Term Care Facilities" notes that in determining whether a long term care facility has a "quality assurance" peer review committee that meets the statutory requirements, a surveyor conducting the investigation may not review peer review protected materials: "Records of the committee meetings identifying quality deficiencies, by statute, may not be reviewed by surveyors unless the facility chooses to provide them." *State Operations Manual*, Appendix PP, "Guidance to Surveyors for Long Term Care Facilities" [Pub. 100-07], available at https://www.cms.gov/Manuals/IOM/list.asp.

C. <u>Federal Law Does Not Preempt the Protections Afforded to Peer Review Documents Under North Carolina State Law.</u>

The PAIMI regulations are clear – peer review protected materials are exempt from disclosure in the context of a P&A agency's investigation, and the PAIMI Act does not preempt State laws governing peer review materials. A brief review of the legislative history of PAIMI confirms that Congress did not intend to preempt state laws protecting the records maintained by peer review committees and instead sought to respect and maintain State peer review protection.

The issue of access to peer review records was raised in both the House and Senate Committee Reports. The House Report states that it is the "Committee's intent that the [PAIMI] Act does not preempt State law regarding disclosure of peer review/medical review records relating to the proceedings of such committees." H.R.Rep. No. 102-319, at 6 (1991), reprinted in 1991 U.S.C.C.A.N. 777, 782. The Senate Report summarized testimony from

various witnesses before the committee, including Dennis R. Jones, the commissioner of the Texas Department of Mental Health and Mental Retardation. S. Rep. 102-114 (1991), 1991 WL 142023, at *3-4. Commissioner Jones testified about "the need to include report language clarifying access to peer review records" and explained that if P&A systems had access to peer review reports it "would reduce the candor about the quality of care by peers." *Id.* at *3. When it enacted this legislation, Congress did not intend to preempt State law that protects the confidentiality of peer review documents. Plaintiff cannot compel Frye Regional to produce the requested peer review committee reports.

D. <u>Defendant's Peer Review Committee Is Not an "Agency" Subject to the</u> Disclosure Requirements Under the PAIMI Act.

The federal regulations require disclosure of reports prepared by an "agency" charged with investigating abuse, neglect or injury occurring at a "facility rendering care or treatment, or by or for the facility itself" 42 C.F.R. § 51.41(c)(2). In an effort to circumvent the peer review protection afforded by both North Carolina law and the PAIMI Act, Plaintiff alleges that because Frye Regional must report alleged abuse committed by a health care provider to the Health Care Personnel Registry, Frye Regional is an investigatory "agency" and is therefore required to turn over any reports or documents generated by the peer review committee during Frye Regional's investigation of C.L.H.'s death.

Neither the statute nor the regulations define an "agency;" however, if the Court were to define "agency" as urged by the Plaintiff, the specific carve out for peer review records would be rendered moot. Furthermore, if "agency" and "facility" are synonymous, the PAIMI Act and regulations would be nonsensical, repetitive, and internally inconsistent. The regulation distinguishes between an investigatory agency and the health care facility or program that is the subject of the investigation, and treats them as two disparate entities. The regulation at 42 C.F.R.

§ 51.41, for example, addresses access by the P&A agency to records and information held by

many separate entities, including the "facility or program rendering treatment," an "agency

charged with investigating abuse, neglect or injury," "individuals or entities performing licensure

or certification reviews," and "professional accreditation organizations." It is a well-recognized

canon of statutory construction that a statute or regulation should be construed so that no part of

the statute is rendered useless or redundant. See, e.g., Porsh Builders, Inc. v. City of Winston-

Salem, 302 N.C. 550, 556, 276 S.E.2d 443, 447 (1981). Plaintiff's strained construction of the

regulatory language should be rejected.

CONCLUSION

For the reasons set forth herein, Frye Regional respectfully requests that its Motion to

Dismiss pursuant to Rule 12(b)(6) be allowed and that this action be dismissed with prejudice.

Respectfully submitted, this the 16th day of August, 2013.

/s/ Laura J. Dildine

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8

CERTIFICATE OF SERVICE

The undersigned hereby certifies that Frye Regional Medical Center Inc.'s Brief in Support of its Motion to Dismiss was electronically filed with the Clerk of Court using the CM/ECF system, which will send notification of such filing to counsel of record at:

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This the 16th day of August, 2013.

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